



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-737]

Schedules of Controlled Substances: Placement of Methiopropamine in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration places *N*-methyl-1-(thiophen-2-yl)propan-2-amine (methiopropamine), including its salts, isomers, and salts of isomers in schedule I of the Controlled Substances Act. This action is being taken to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess) or propose to handle methiopropamine.

DATES: Effective date: [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Dr. Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362-3249.

SUPPLEMENTARY INFORMATION:

Legal Authority

The United States is a party to the 1971 United Nations Convention on Psychotropic Substances (1971 Convention), February 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175, as amended. Procedures respecting changes in drug schedules under the 1971 Convention are governed domestically by 21 U.S.C. 811(d)(2)-(4). When the United States receives notification of a scheduling decision pursuant to Article 2 of the 1971 Convention adding a drug or other substance to a specific schedule, the Secretary of the Department of Health and Human Services (HHS),¹ after consultation with the Attorney General, shall first determine whether existing legal controls under subchapter I of the Controlled Substances Act (CSA) and the Federal Food, Drug, and Cosmetic Act meet the requirements of the schedule specified in the notification with respect to the specific drug or substance. 21 U.S.C. 811(d)(3). In the event that the Secretary of HHS (Secretary) did not so consult with the Attorney General, and the Attorney General did not issue a temporary order, as provided under 21 U.S.C. 811(d)(4), the procedures for permanent scheduling are set forth in 21 U.S.C. 811(a) and (b). Pursuant to 21 U.S.C. 811(a)(1), the Attorney General, by rule, may add to such a schedule any drug or other substance, if he finds that such drug or other substance has a potential for abuse, and makes with respect to such drug or other substance the findings prescribed by 21 U.S.C. 812(b) for the schedule in which such drug is to be placed. The Attorney General has delegated this scheduling authority to the Administrator of the Drug Enforcement Administration (DEA Administrator or Administrator). 28 CFR 0.100.

Background

¹ As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the Controlled Substances Act, with the concurrence of NIDA. 50 FR 9518 (March 8, 1985). The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460 (July 1, 1993).

Methiopropamine is a central nervous system (CNS) stimulant and is structurally related to the schedule II stimulants methamphetamine and amphetamine.

Methiopropamine is not approved by the Food and Drug Administration for use in the United States. On March 16, 2017, the Commission on Narcotic Drugs voted to place *N*-methyl-1-(thiophen-2-yl)propan-2-amine (methiopropamine) in Schedule II of the 1971 Convention (CND Dec/60/8) during its 60th session.

DEA and HHS Eight Factor Analyses

On August 27, 2020, in accordance with 21 U.S.C. 811(b), and in response to DEA's November 20, 2018, request, HHS provided to DEA a scientific and medical evaluation and scheduling recommendation for methiopropamine. DEA reviewed HHS's evaluation and recommendation for schedule I placement, and all other relevant data, and conducted its own eight-factor analysis stipulated in 21 U.S.C. 811(c). DEA found, under 21 U.S.C. 812(b)(1), that this substance warrants control in schedule I. Both DEA and HHS eight-factor analyses are available in their entirety under the tab "Supporting Documents" of the public docket of this rulemaking action at <https://www.regulations.gov>, under docket number "DEA-737."

Notice of Proposed Rulemaking to Schedule Methiopropamine

On September 2, 2021 (86 FR 49267), DEA published a notice of proposed rulemaking (NPRM) to permanently control methiopropamine in schedule I. Specifically, DEA proposed to add methiopropamine to 21 CFR 1308.11(f) (the stimulants category of schedule I). The NPRM provided an opportunity for interested persons to file a request for hearing in accordance with DEA regulations on or before October 4, 2021. No requests for such a hearing were received by DEA. The NPRM also provided an opportunity for interested persons to submit comments on or before October 4, 2021.

Comments Received

In response to the NPRM, DEA received four comments. Three of the submissions were from individuals or anonymous commenters. Of these three, two commenters provided support for the NPRM, and one opposed the NPRM. A fourth comment was either submitted or posted to the wrong docket as it involved a different DEA rulemaking. As such, the fourth comment is outside the scope of this current scheduling action.

Support for NPRM

Two commenters were in support of this rulemaking. One stated that methiopropamine is a stimulant and a user can get high from it, so it should be a controlled substance. The second commenter stated that if there is not an accepted medical use, then it should be a schedule I substance.

DEA Response: DEA appreciates the comments in support of this rulemaking.

Opposition to NPRM

One commenter opposed the NPRM to control methiopropamine as a schedule I drug. The commenter stated that scheduling methiopropamine will only expand the number of people in the United States who can be captured in the mass incarceration net. The commenter thought the approach should not be a criminal issue but a public health issue.

DEA Response: Substances are scheduled to protect the public health and provide safety for individuals. Thus, pursuant to 21 U.S.C. 811(a), the CSA authorizes DEA's Administrator, under authority delegated by the Attorney General, to control any drug or other substance if the Administrator finds that the drug or other substance has a potential for abuse, and makes with respect to such drug or other substance the findings prescribed by 21 U.S.C. 812(b).

Scheduling Conclusion

After consideration of the public comments, scientific and medical evaluation and accompanying recommendation of HHS, and after its own eight-factor evaluation, DEA finds that these facts and all other relevant data constitute substantial evidence of the potential for abuse of methiopropamine. DEA is permanently scheduling methiopropamine as a controlled substance under the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of HHS and review of all other available data, the Administrator, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

1. Methiopropamine has a high potential for abuse

Methiopropamine, similar to the schedule II stimulants amphetamine and methamphetamine, is a CNS stimulant with a high potential for abuse. Data from animal behavioral locomotor studies show that methiopropamine produces stimulation similar to that of methamphetamine. As HHS mentions, methiopropamine abuse in humans has been reported in at least 16 countries, including some countries in North America and Europe. Additionally, typical stimulant effects such as euphoria, psychomotor stimulation, and anxiety have been described from self-reports of methiopropamine abusers. These effects are similar to those of schedule II stimulants such as methamphetamine and amphetamine. These data collectively indicate that methiopropamine has a high potential for abuse similar to other schedule II stimulants such as amphetamine and methamphetamine.

2. Methiopropamine currently has no accepted medical use in treatment in the United States

According to HHS, FDA has not approved a marketing application for a drug product containing methiopropamine for any therapeutic indication. As HHS states, there are also no clinical studies or petitioners that claim an accepted medical use in the United States. Thus, methiopropamine has no currently accepted medical use in treatment in the United States.²

3. There is a lack of accepted safety for use of methiopropamine under medical supervision

The safety of methiopropamine or use under medical supervision has not been determined because it has no approved medical use in treatment in the United States and has not been investigated as a new drug. Therefore, there is a lack of accepted safety for use of methiopropamine under medical supervision.

Based on these findings, the Administrator concludes that methiopropamine (chemical name: *N*-methyl-1-(thiophen-2-yl)propan-2-amine), including its salts, isomers, and salts of isomers, warrants control in schedule I of the CSA.

21 U.S.C. 812(b)(1).

Requirements for Handling Methiopropamine

Methiopropamine is subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, engagement in research, and conduct of instructional activities or chemical analysis with, and possession of schedule I controlled substances, including the following:

² Although there is no evidence suggesting that methiopropamine has a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by FDA, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated: i. The drug's chemistry must be known and reproducible; ii. there must be adequate safety studies; iii. there must be adequate and well-controlled studies proving efficacy; iv. The drug must be accepted by qualified experts; and v. the scientific evidence must be widely available. 57 FR 10499 (1992), pet. for rev. denied, *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1135 (D.C. Cir. 1994).

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) methiopropamine, or who desires to handle methiopropamine must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. Any person who currently handles methiopropamine and is not registered with DEA must submit an application for registration and may not continue to handle methiopropamine, unless DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

2. *Disposal of stocks.* Any person unwilling or unable to obtain a schedule I registration must surrender or transfer all quantities of currently held methiopropamine to a person registered with DEA before the effective date of a final scheduling action in accordance with all applicable Federal, State, local, and tribal laws. Methiopropamine must be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable Federal, State, local, and tribal laws.

3. *Security.* Methiopropamine is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 823 and in accordance with 21 CFR 1301.71–1301.76, as of the effective date of this final scheduling action. Non-practitioners handling methiopropamine must also comply with the employee screening requirements of 21 CFR 1301.90-1301.93.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of methiopropamine must comply with 21 U.S.C. 825, and be in accordance with 21 CFR part 1302.

5. *Quota.* Only registered manufacturers are permitted to manufacture methiopropamine in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

6. *Inventory.* Every DEA registrant who possesses any quantity of methiopropamine must take an inventory of methiopropamine on hand at that time, pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (d).

Any person who registers with DEA must take an initial inventory of all stocks of controlled substances (including methiopropamine) on hand on the date the registrant first engages in the handling of controlled substances pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (b).

After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including methiopropamine) on hand every two years, pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant must maintain records and submit reports for methiopropamine, or products containing methiopropamine, pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1301.74(b) and (c) and 1301.76(b) and parts 1304, 1312, and 1317. Manufacturers and distributors must submit reports regarding methiopropamine to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

8. *Order Forms.* Every DEA registrant who distributes methiopropamine must comply with the order form requirements, pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305.

9. *Importation and Exportation.* All importation and exportation of methiopropamine must comply with 21 U.S.C. 952, 953, 957, and 958, and be in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving methiopropamine not authorized by, or in violation of, the CSA or its implementing regulations is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 and 13563 (Regulatory Planning and Review; Improving Regulation and Regulatory Review)

In accordance with 21 U.S.C. 811(a), this final scheduling action is subject to formal rulemaking procedures performed “on the record after opportunity for a hearing,” which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the procedures and criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–612, has reviewed this final rule, and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities.

DEA is placing the substance methiopropamine (chemical name: *N*-methyl-1-(thiophen-2-yl)propan-2-amine), including its salts, isomers, and salts of isomers, in schedule I of the CSA. This action is being taken to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle methiopropamine.

According to HHS, methiopropamine has a high potential for abuse, has no currently accepted medical use in treatment in the United States, and lacks accepted safety for use under medical supervision. DEA's research confirms that there is no legitimate commercial market for methiopropamine in the United States. Therefore, DEA estimates that no United States entity currently handles methiopropamine and does not expect any United States entity to handle methiopropamine in the foreseeable future. DEA concludes that no legitimate United States entity would be affected by this rule. As such, this rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the “Regulatory Flexibility Act” section above, DEA has determined pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995 (2 U.S.C. 1501 *et seq.*) that this final rule would not result in any Federal mandate

that may result “in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year * * * .” Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of the final rule to the Government Accountability Office, the House, and the Senate.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

2. Amend § 1308.11 by:

- a. Redesignating paragraphs (f)(9) through (11) as (f)(10) through (12); and
- b. Adding a new paragraph (f)(9).

The addition reads as follows:

§ 1308.11 Schedule I.

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(f) * * *

(9) Methiopropamine (*N*-methyl-1-(thiophen-2-yl)propan-2-amine)..... 1478

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Signing Authority

This document of the Drug Enforcement Administration was signed on November 14, 2022, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the Federal Register.

Scott Brinks,
Federal Register Liaison Officer,
Drug Enforcement Administration.

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